****NOT FOR PUBLICATION****

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC., *et al.*, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendant.	Civ. No. 12-5374 (FLW) **OPINION**

In this claim construction Opinion, the Court construes a patent for certain methods of using a pharmaceutical compound, ganirelix acetate. After reviewing the parties' briefing and exhibits, and holding a *Markman* hearing, the Court construes the disputed claim terms in accordance with the intrinsic and extrinsic evidence, as set forth herein.

I. BACKGROUND

Plaintiffs Merck & Co., Inc. ("Merck"), Organon USA, Inc., Merck Sharp & Dohme, B.V., (collectively, "Merck Plaintiffs") and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs") brought the instant patent infringement suit against Defendant Sun Pharmaceutical Industries, Ltd. ("Defendant" or "Sun"), through a Complaint filed on August 27, 2012. At issue in this *Markman* proceeding is U.S. Patent No. 5,767,082 (the "'082" Patent), which is

owned by Roche and licensed to the Merck Plaintiffs, and follows research and development by all Plaintiffs.[1]

The '082 Patent concerns a pharmaceutical compound called "ganirelix," which, as explained in more detail *infra*, affects hormones associated with female mammalian ovulation and pregnancy. The '082 Patent does not claim the ganirelix compound itself; rather it claims certain methods of using ganirelix through a "ganirelix acetate injection." Plaintiffs have received FDA approval to market ganirelix acetate injection for use during *in vitro* fertilization, specifically, in connection with a procedure called "controlled ovarian hyperstimulation." During a normal ovulation cycle, a single ovarian follicle grows to produce a single egg. When this follicle matures, and thus contains an egg, certain hormone levels peak, which causes receptors sensitive to "gonadotropin-releasing hormone" ("GnRH") to signal the pituitary gland to release "luteinizing hormone" ("LH").[2] As is pertinent to this matter, LH then triggers female ovulation, *i.e.*, LH causes the follicle to rupture and release the egg into the ovary.

In contrast, during controlled ovarian hyperstimulation, as part of *in vitro* fertilization, the woman is administered a growth hormone called "follicle stimulating hormone" ("FSH") to stimulate the growth of multiple ovarian follicles, instead of the usual one, with the hopes that increased follicle production will result in increased egg production for use in the *in vitro* process. However, this process is complicated by the fact that treatment with FSH alone often causes a rise in other hormones, including a rise in LH. Because the increased amount of LH

[1] The Complaint also alleges infringement of U.S. Patent No. 6,653,286 (the "'286 patent"), which is owned by Plaintiff Merck Sharp & Dohme B.V. According to Plaintiffs, the '286 patent is directed a certain dosing and use of the compound claimed by the '082 patent. *See Pl. Opening Br.* at 4. The '286 patent is not at issue in this *Markman* hearing, as the parties have stipulated to the construction of claims, and will not be addressed further in this Opinion.

[2] For this reason, GnRH is alternatively referred to as "luteinizing-releasing hormone" ("LHRH"). As the parties typically refer to GnRH as such, I employ the same in this Opinion.

could cause follicles to rupture prior to egg maturity, one of the goals in the *in vitro* process is to prevent early release of LH. Plaintiffs accomplish this through their '082 Patent. Ganirelix acetate injections are administered to the female along with FSH in controlled ovarian hyperstimulation.

As used in the in the FDA approved indication, ganirelix acetate acts as a GnRH "antagonist," effectively blocking GnRH receptors and preventing the pituitary gland from prematurely releasing LH.[3] Once the administration of FSH ceases, so too does the administration of ganirelix acetate injections. The follicles are allowed to rupture and release their eggs, and doctors then harvest the mature eggs for the next step in the *in vitro* fertilization process.

The instant litigation arises because Sun filed an Abbreviated New Drug Application ("ANDA") with the FDA to market a generic version of ganirelix acetate for use in *in vitro* fertilization. According to Sun, its ANDA does not infringe on the '082 Patent because it argues that nothing in that patent claims a method of using ganirelix acetate injections for *in vitro* fertilization; instead, Sun contends, the '082 Patent only claims methods of using ganirelix acetate injections for contraceptive purposes. Plaintiffs vigorously dispute this reading of the '082 Patent. This is the sole issue before the Court in this claim construction proceeding.

[3] Prior to the use of ganirelix acetate injections, doctors would attempt to prevent premature LH release through the use of GnRH "agonists." Unlike GnRH antagonists, which block the hormone receptors, agonists act on the receptors, but in a way that desensitizes the receptors. Once the receptors are desensitized, they will not trigger the release of LH even with heightened levels of FSH. Thus, the ultimate effect of GnRH antagonists and agonists are the same; the difference is that GnRH agonists must be administered much more frequently and for a longer duration than antagonists, with more severe side effects.

II. LEGAL STANDARDS

Claims define the scope of the inventor's right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc). Indeed, the court can only interpret claims, and "can neither broaden nor narrow the claims to give the patentee something different than what he has set forth" in the specification. *E.I. Du Pont de Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman*, 52 F.3d at 986 ("[T]he focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."); *Phillips*, 415 F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (*e.g.*, the patent, its claims, the specification and prosecution history) and extrinsic evidence (*e.g.*, expert reports, testimony and anything else). *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

In interpreting the disputed terms, it is well settled that the Court should look first to the intrinsic evidence. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Phillips*, 415 F.3d at 1313-14. Generally, words in patent claims are given their "ordinary and accustomed meaning as understood by one of ordinary skill in the art" at the priority date of the patent application. *Dow Chem.*, 257 F.3d at 1372; *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362 (Fed. Cir. 1999). The claims must be construed objectively in the context of both the

particular claim and the entire patent because "the claims themselves provide substantial guidance as to the meaning of particular claim terms," and claim terms are normally used consistently throughout the patent. *Phillips*, 415 F.3d at 1313-14.

In that regard, courts are instructed to look to the specification, which is a written description of the invention. "[C]laims 'must be read in view of the specification, of which they are a part.'" *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). Indeed, the specification is perhaps the single best guide to the meaning of a claim term due to its statutory requirements of being in "full, clear, concise, and exact terms." *Id.* at 1316; *see* 35 U.S.C. § 112. "The specification acts as a dictionary when it expressly" or implicitly defines terms used in the claims. *Phillips*, 415 F.3d at 1321. Thus, it effectively limits the scope of the claim. *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006). Due to its nature, "the specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive.'" *Id.* (quoting *Vitronics Corp.*, 90 F.3d at 1582).

Extrinsic evidence includes all evidence external to the patent and prosecution history, *i.e.*, expert and inventor testimonies, dictionaries, and learned treaties. *Markman*, 52 F.3d at 980. It is considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. *See Vitronics*, 90 F.3d at 1583; *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). In that regard, the Federal Circuit cautioned, in *Phillips*, that dictionary definitions should not be used to interpret patent claim terms in a manner that is divorced from the context and description of the invention in the specification. *Phillips*, 415 F.3d at 1321. The *Phillips* court reasoned that because of the nature of the patent claims, dictionary definitions, as extrinsic evidence, are usually less reliable than the patent documents themselves in establishing the ordinary meaning of a claim

term. *Id.* at 1314; *Toro Co. v. White Consol. Indus.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999). Ultimately, extrinsic evidence cannot be used to vary or contradict claim terms when their meanings are discernible from intrinsic evidence. *C. R. Bird, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004).

Overall, in construing the claims, "[t]he judge's task is not to decide which of the adversaries is correct. Instead, the judge must independently assess the claims, the specification, and if necessary the prosecution history, and relevant extrinsic evidence, and declare the meaning of the claims." *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1556 (Fed. Cir. 1995); *MEMS Technology Berhad v. International Trade Com'n*, 447 Fed. App'x 142, 153 (Fed. Cir. 2011) (same).

III. DISCUSSION

The sole dispute in this *Markman* proceeding is the proper construction of the terms: "A method of inhibiting ovulation in a female mammalian subject"/"A method of inhibiting ovulation in a mammalian female subject",[4] as illustrated by the chart below.

[4] The first formulation of the claim language appears in Claims 1 and 2, while the second formulation appears in Claim 3. Neither party places any significance for claim construction purposes on the transposition of "female mammalian" with "mammalian female" between the different claims, and accordingly, I analyze this language in all three claims same.

Disputed claim language: "A method of inhibiting ovulation in a female mammalian subject"/ "A method of inhibiting ovulation in a mammalian female subject"	
Plaintiffs' proposed construction:	**Sun's proposed construction:**
• No construction needed; plain and ordinary meaning applies. • Alternatively: "a method of preventing or delaying ovulation in a female mammalian subject"	• "a method of female contraception" • Alternatively: "a method of female contraception by ovulation prevention or delay"

As evidenced by the parties' proposed constructions, the core dispute is whether this claim language in the '082 Patent should be construed broadly to cover both pro- and anti-fertility uses, as Plaintiffs contend, or narrowly to cover only contraceptive uses, as Sun contends. In that connection, Plaintiffs assert that the plain and ordinary meaning of the claim language covers the method of using ganirelix acetate injections to delay ovulation for both contraceptive and *in vitro* fertilization ("IVF") purposes, and nothing in the specification or extrinsic evidence supports the more limited construction raised by Sun. Indeed, Plaintiffs contend that Sun's narrower construction requires importing limitations into the claim from the specification, which runs counter to Federal Circuit precedent. Moreover, Plaintiffs argue that Sun's construction itself is not self-explanatory and would require further construction to ascertain the scope of the claim. In contrast, Sun argues that under an analysis carried out in line with the Federal Circuit's decision in *Phillips*, the only proper construction for this claim language is limited to contraceptive, or anti-fertility, purposes. Specifically, Sun argues that by examining, in the following order, the (i) claim language (ii) language of the specification, (iii) intrinsic sources cited in the specification, and (iv) extrinsic sources and expert testimony, it is apparent that the disputed claim language in the '082 Patent covers only methods of

contraception. Sun further supports its construction by arguing that a person of ordinary skill in the art at the time the '082 Patent was filed—1987—would not have considered the disputed claim language to encompass IVF, a proposition that Plaintiffs' vigorously dispute.[5] In light of the foregoing arguments, it is clear that the fundamental issue is the meaning of the term "inhibiting ovulation," as viewed through the lens of the claim language and specification by one of ordinary skill in the art—a reproductive endocrinologist[6]—in 1987. *See Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d at 1372.

I begin, as I must, with the language of the claim itself, *see id.*, which provides in full:

> *A method of: inhibiting ovulation in a female mammalian subject*; preventing ovarian hyperstimulation in response to exogenous gonadotropins in a female human subject; treating premenstrual syndrome in a female human subject; treating endometriosis in a female human subject; treating prostatic hypertrophy in a male mammalian subject; inhibiting spermatogenesis in a male mammalian subject; treating precocious puberty in a human subject; interrupting heat in a female animal subject; or terminating pregnancy in a female mammalian subject; which method comprises administering to said subject an effective amount of [ganirelix acetate] . . . .

---

[5] I note that Sun objects to the "plain and ordinary meaning" construction proposed by Plaintiffs, arguing that such a construction is tantamount to no construction at all. I disagree. Where parties dispute a term that has a "plain and ordinary meaning," *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010), "a court has the duty to resolve the parties' claim construction disputes so the issues are not litigated before the jury." *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). Such a duty, however, does not require the Court to reject the "plain and ordinary meaning," indeed, in some instances, the court may discharge its duty by rejecting the challenging party's proposed construction. *See Finjan*, 626 F.3d at 1206-07.

Sun also challenges Plaintiffs' proposed construction on the grounds that it raises questions of enablement and, for that reason alone, should be rejected. I address this aspect of Sun's argument *infra*.

[6] The parties agree that a person of ordinary skill in the art is someone with training in reproductive endocrinology. *See Markman* Tran., T30:25-T31:6 ("[O]ne place [the parties] agree . . . is that [a person of ordinary skill in the art] would be someone with training in reproductive endocrinology . . . a medical specialist who spends his or her time in that field and specifically assisting [a] woman who cannot otherwise get pregnant naturally. That is the knowledge that would be brought to this patent.").

'082 Patent, Claim 1, 2, 3 (emphasis added).[7] The claim language and context sheds little light on the meaning of the disputed terms. Plaintiffs point out that the inventors used the term "inhibiting" in some portions of the claim, and the term "preventing" in other portions, and argue that, absent evidence to the contrary, the presumption is that different words have different meanings—that is, that the word "inhibiting" must mean something more than "preventing," as would be the case under Sun's proposed construction. *Becton, Dickinson & Co. v. Tyco Healthcare*, 616 F.3d 1249, 1254 (Fed Cir. 2010) ("In the absence of any evidence to the contrary, [a court] must presume that the use of . . . different terms in the claims connotes different meanings."); *see also Cortland Line Co. v. Orvis Co.*, 203 F.3d 1351, 1356 (Fed. Cir. 2000) ("Claim terms receive their ordinary and customary meaning unless the patentee assigns a special meaning."). In that connection, Plaintiffs rely on testimony from their expert, Dr. Zev Rosenwaks, as well as a medical dictionary, defining the term "inhibiting ovulation" as "preventing or delaying ovulation." *See* Rosenwaks Decl., ¶¶ 33-40; Ex. 5 (Stedman's Medical Dictionary (26th ed. 1995). Although such an approach initially appears to demonstrate the meaning of the disputed term as understood by a person of ordinary skill in the art, I find it inappropriate to proceed directly to extrinsic evidence consisting of expert testimony and dictionary definitions before examining the remaining intrinsic evidence.[8] Thus, because of this

[7] As noted *supra* Footnote 4, the language in Claim 3 is identical to Claims 1 and 2 except that it is phrased as a "mammalian female subject."

[8] Moreover, Sun argues that the claim uses the word "inhibit" in another instance: "inhibiting spermatogenesis." Sun asserts that this term is the equivalent of male contraception, and thus, reading like words the same, Sun contends that the same interpretation of "inhibit" should be applied to "inhibiting ovulation," *i.e.*, the equivalent of female contraception. Sun's assertion, however, is based on argument only. Sun provides no evidence from the '082 patent that defines "inhibiting spermatogenesis" as related to contraception only, let alone equates this term with "inhibiting ovulation." Thus, I do not find the repeated use of the word "inhibiting" in these two claim terms to be dispositive of their meaning. Nevertheless, Sun's argument

ambiguity in the claim itself, I must turn to the intrinsic evidence before relying on Plaintiffs' extrinsic evidence to ascertain the contours of the disputed claim term. *See Vitronics Corp.*, 90 F.3d at 1582 (explaining that "in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification"); *Phillips*, 415 F.3d at 1315 ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive . . . ." (Internal quotation marks omitted.)).

I begin with the language of the specification, which provides several insights into the meaning of the term "inhibiting ovulation." First, the specification identifies, *inter alia*, the following utilities as "flowing from the antagonist effects of ganirelix acetate injections: (i) "female contraception"; and (ii) "ovulation prevention or delay." '082 Patent, Col. 11, lns. 44-47. Again, in line with the proposition that different terms should be given different meanings, the identification of these two uses of ganirelix acetate injections suggests that the patent authors viewed "contraception" as distinct from "ovulation prevention or delay," and that if they intended to limit their claim to a method of female contraception, as Sun suggests, they would have used the term "contraception" rather than "ovulation prevention or delay." Similarly, in the following column of the specification, the authors describe a use of ganirelix acetate injections for "inhibition of ovulation," and then, several lines later, describe a method of administering ganirelix acetate that is particularly effective for "contraception." *Id.* at Col. 12, lns. 26-30, 44-45. Again, Plaintiffs argue that this portion of the specification further demonstrates that the authors intended to the term "inhibiting ovulation" to convey a meaning different than "contraception." This alone militates against reading a limitation into the claim

---

demonstrates that the meaning of the disputed claim term cannot be discerned from the claim language alone.

term, as I must presume that different terms have different meanings. *Becton, Dickinson & Co., LP*, 616 F.3d at 1254.

Notwithstanding the foregoing, Sun argues that the specification only employs language directly or indirectly associated with contraception and thus anti-fertility, and hence the term "ovulation prevention or delay," when read in this context, can only relate to anti-fertility applications. In support, Sun relies on a portion of the specification, entitled "Background of the Invention", that recites examples of uses of GnRH antagonists to "block ovulation," "induce abortion," and "prevent[] pregnancy in animals." '082 Patent, Col. 1, lns. 26-35. Sun further points out that the only explicit reference in the specification to IVF concerns "ovarian hyperstimulation syndrome," which Sun characterizes as a serious medical condition unrelated to the procedure of controlled ovarian hyperstimulation for which the parties seek to use ganirelix acetate—indeed, at the *Markman* hearing, the parties acknowledged that they are not relying on any method claimed in the '082 Patent relating to ovarian hyperstimulation syndrome. *See Markman* Hearing, T58:13-23 (explaining that "there is no dispute in this case that the prevention of ovarian hyperstimulation is entirely distinct from controlled ovarian hyperstimulation").[9]

---

[9] As Sun's counsel clarified:

> There are nine specific methods claimed in the patent. [Ovarian hyperstimulation syndrome] is a method that doesn't relate to the method of inhibiting ovulation. The passage [of the specification] which talks about a normal degree of ovarian stimulation, what they are referring to is, you are not going to have hyperstimulation, which is the syndrome. They are not talking about premature LH surges here. They are not even talking about synchronization of ovulation. They are talking about preventing an incredibly dangerous result, ovarian hyperstimulation, and that's all this paragraph [Col. 12, lns. 11-25] is talking about.

I disagree with Sun's reading of the specification. To begin, the language that Sun relies most heavily on is drawn from the introductory portion of the specification, under the heading "Background of the Invention"; this section is intended to illuminate the state of the art that exists prior to the invention claimed in the patent. *See, e.g.*, *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1144 (Fed. Cir. 2012) (noting that the "Background of the Invention" portion of the patent speaks to the prior art). For that reason, I find that this portion of the specification is only marginally helpful in ascertaining the scope of the claim terms. Moreover, contrary to Sun's argument, in addition to describing contraceptive uses of GnRH antagonists, the background section also notes more broadly that GnRH antagonists "are useful in the control of fertility," '082 Patent, Col. 1, lns. 26-27, which, as explained in more detail *infra*, could be read to extend to both contraceptive and pro-fertility purposes. Beyond the background section, I also find that the specification speaks to both contraceptive and pro-fertility uses. For example, the specification recites that one of the uses of GnRH antagonists is for "synchronization of ovulation." *Id.* at Col. 11, ln. 52. As the parties' experts agree, synchronization of ovulation is associated with a pro-fertility use of GnRH antagonists. *See* Rosenwaks Dep., T48:24-T49:2; Carr Dep., T80:16-T81:1. Thus, I do not find that the language of the specification itself supports Sun's limited construction.

Sun further argues that, apart from the language of the specification, two articles cited in, and thereby incorporated by reference into, the specification, demonstrate that the inventors of the '082 Patent intended the term "inhibiting ovulation" to encompass only anti-fertility because

---

Markman Tran., T61:11-25. I agree with Sun's reading of this portion of the specification, finding that it refers to the claimed method of preventing ovarian hyperstimulation syndrome, and not to a method of "inhibiting ovulation." Accordingly, I do not rely on this aspect of the specification in construing the meaning of the disputed claim term.

these articles address contraceptive uses of GnRH antagonists. The first article appears in the specification as explaining that "[a] primary measure of LHRH antagonist potency is the ability to inhibit ovulation in rats, as assayed by the procedure of Corbin. A and Beattie. C.W., *Endocrine Res. Commun.*, 2:1 (1975)." '082 Patent, Col. 11, lns. 21-24 (the "Corbin & Beattie" article). Similarly, an article by Vickery. B. H.—also one of the authors of the '082 Patent—in *Endocrine Reviews*, 7:115 (1986), is provided in the specification as identifying additional uses and utilities for ganirelix acetate as a GnRH antagonist. '082 Patent, Col. 11, lns. 45 to Col. 12, lns. 12 (the "Vickery" article). Sun argues that (i) the Corbin & Beattie article pertains solely to using GnRH antagonists as a contraceptive, and similarly (ii) the Vickery article discusses how GnRH antagonists pre-dating ganirelix (as well as GnRH agonists) were primarily envisioned for anti-fertility uses. According to Sun, these articles demonstrate that the authors did not envision any pro-fertility uses of ganirelix—and thus, Sun argues, its proposed construction limiting the claim language "inhibiting ovulation" to anti-fertility uses is supported by this aspect of the intrinsic record.

With respect to the Corbin & Beattie article, Sun argues, and Plaintiffs do not dispute, that this article only addresses the use of a GnRH antagonist for contraceptive purposes. Sun further contends that terms such as "inhibit ovulation," "preventing ovulation," pregnancy inhibition" and "ovulation . . . delayed," are used throughout the article interchangeably to describe animal contraception only. Thus, Sun contends, because the Corbin & Beattie article uses the term "inhibit ovulation" only in connection with contraception, and because the '082 Patent authors referenced this article in the specification, it follows that the term "inhibit ovulation" in the '082 Patent only refers to contraception. Sun further argues that because the Corbin & Beattie article equates the terms "inhibit" with "delay" or "prevent," and only uses

these terms in the context of contraception, the Court should reject Plaintiffs' proposed construction that the disputed claim term "inhibit ovulation" encompasses pro-fertility uses.

Several problems exist with Sun's reasoning in this regard. As noted above, the Corbin & Beattie article is only referenced once in the '082 Patent as setting forth a means of measuring GnRH antagonist potency. '082 Patent, Col. 11, lns. 21-24. This limited citation to the article, for a specific purpose—one means of measuring potency of the compound of the invention—is not enough to show that the inventors intended the referenced article to serve as a limitation on the claims. *See MBO Labs., Inc.*, 474 F.3d at 1333-34 ("Limiting claims from the specification is generally not permitted absent a clear disclosure that the patentee intended the claims to be limited as shown." (Citing *Phillips*, 415 F.3d at 1323)). I therefore find it inappropriate to adopt Sun's argument that this article was intended to limit the term "inhibiting ovulation" to only contraceptive purposes. The specification and patent file history do not disclose that the Corbin & Beattie article reference was intended as anything other than showing a means for assessing potency. *See Laryngeal Mask Co.*, 618 F.3d at 1372. In the same vein, the mere fact that the Corbin & Beattie article interchangeably uses the terms "inhibiting," "prevention," and "delay" in connection with contraceptive uses of GnRH antagonists does not mean that the inventors employed the same interchangeable meaning in the '082 Patent. The '082 Patent is broader in scope than the Corbin & Beattie article, in that the patent claims uses of GnRH antagonists beyond the contraceptive use assessed in the article—a point not disputed by the parties in this case. Again, given the limited purpose for which the Corbin & Beattie article was referenced in the '082 Patent, there is no basis to import the same meanings used in that article into the claim terms. *See id.* For these reasons, I reject Sun's contention that the reference to the Corbin & Beattie article in the '082 Patent illuminates the meaning of the disputed claim term.

Sun's second argument pertains to the Vickery article—which, as noted, is authored by one of the '082 Patent inventors—and which is referenced and incorporated into the '082 Patent as setting forth other uses for GnRH antagonists in addition to those explicitly listed in the patent specification.[10] Sun points out that the Vickery article refers to "ovulation suppression" as a contraceptive indication, separate and distinct from another indication for "*in vitro* fertilization," and argues that this differentiation means that the '082 Patent term "inhibiting ovulation" should also be read as only pertaining to contraception. Put differently, Sun contends that "ovulation suppression" and "inhibiting ovulation" are terms with equivalent meaning, and thus the reference to the Vickery article in the '082 Patent demonstrates that the inventors intended to incorporate that meaning into the claim language.

Again, Sun's argument is misplaced. Here, the specification relies on the Vickery article to set forth additional uses of GnRH antagonists not specifically identified in the '082 Patent specification. *See* '082 Patent, Col. 12, lns. 8-10 ("[A]nd other uses [of GnRH antagonists] as set forth in Vickery . . . ."). As was the case with the Corbin & Beattie article, there is nothing in the '082 Patent that shows the authors intended to adopt the same definitions of the Vickery article; rather, the article is cited for the purpose of identifying possible uses of

[10] The specification provides that the following utilities flow from GnRH antagonists: female contraception; ovulation prevention or delay; pregnancy termination in domestic animals and pets; induction of parturition; synchronization of ovulation; estrus suppression; growth promotion in female animals; luteolysis, menses induction; therapy for premenstrual syndrome; therapy for precocious puberty; therapy for uterine leiomyoma; early, first trimester abortifacient; therapy for endometriosis; therapy for mammary tumors and cysts; therapy for polycystic ovary syndrome/disease; therapy for uterine carcinoma; therapy for benign prostatic hypertrophy and for prostatic carcinoma; male contraception; therapy for diseases which result from excessive gonadal production in either sex; functional castration in male food producing animals; suppression of proestrous bloody discharge in dogs; diagnostic utilities, such as predisposition to osteoporosis; and prevention of ovarian hyperstimulation. '082 Patent, Col. 11, ln. 45 to Col. 12, ln. 7.

the claimed invention. Indeed, there is nothing in either the Vickery article or the '082 Patent showing that "inhibiting ovulation" necessary means, and only means, "ovulation suppression," as Sun argues. The general rule is that, absent evidence to the contrary, different words are not intended to have the same meaning. *Becton, Dickinson & Co.*, 616 F.3d at 1254. Therefore, without more, I find it inappropriate to limit the claim language based on the Vickery article. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333-34 (Fed. Cir. 2007) (citing *Phillips*, 415 F.3d at 1323); *see also Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part.").

If anything, the Vickery article supports Plaintiffs' position that the '082 Patent authors intended the disputed claim language to cover both contraceptive and pro-fertility uses of GnRH antagonists. Table 2 of the Vickery article identifies both "ovulation suppression" and "*in vitro* fertilization" as uses of GnRH analogs—*i.e.*, GnRH agonists and antagonists. In that connection, the article explains: "The most imaginative possibility [of GnRH analogs], however, lies in induction of ovulation, particularly for purposes of *in vitro* fertilization and embryo transfer (70). In this case, the *GnRH analog is used to suppress ovarian function* . . . ." Carr Decl., Ex. H at 4 (emphasis added). These portions of the Vickery article undermine Sun's arguments for two reasons. First, the use of the term "suppress" in connection with IVF shows that, contrary to Sun's argument, the Vickery article did not necessarily intend the term "suppress" to refer only to contraception; instead, suppression of ovulation can relate both to contraceptive and fertility uses of GnRH antagonists. Second, because the '082 Patent relied on the Vickery article to identify all

possible uses of GnRH antagonists, the article's reference to IVF procedures as one potential use of GnRH antagonists militates against a finding that the '082 Patent authors intended to limit the claims to only contraceptive uses. For these additional reasons, I reject Sun's argument that the Vickery article defines or limits the disputed claim term to contraception only.

Sun points to nothing else in the intrinsic evidence that supports adopting a limiting construction for the disputed claim term. As noted above in connection with the Vickery and Corbin & Beattie articles, the term "inhibiting ovulation" is not unambiguously or consistently used to refer only to contraceptive practices, as Sun suggests. Again, the lack of intrinsic evidence that the '082 Patent authors sought to exclude pro-fertility uses of their claimed invention, combined with a state of the art where GnRH antagonists were understood to have IVF-related uses, strongly militates against limiting the disputed claim term to "a method of female contraception." *See Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301-1302 (Fed. Cir. 2003) ("Where, as here, the written description and prosecution history fail to express a manifest exclusion or restriction limiting the claim term, and where the written description otherwise supports the broader interpretation, we are constrained to follow the language of the claims, and to give the claim term its full breadth of ordinary meaning as understood by persons skilled in the relevant art." (Citations and internal quotation marks omitted.); *cf. SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question."). Thus, I reject Sun's argument that its proposed, limiting construction is supported by the intrinsic evidence.

Having determined that the intrinsic evidence does not support Sun's position, and instead supports a broader construction, I need not progress to Sun's additional reliance on extrinsic evidence in support of a limited construction.[11] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Nevertheless, I find that review of the state of the art in 1987 reveals that a person skilled in the art would recognize that GnRH antagonists could have pro-fertility uses, arising from temporary ovulation suppression or delay, as evidenced both by the intrinsic evidence of the Vickery article—published in 1986—and the testimony and reports of the parties' experts, as detailed in the following analysis.

First, Sun acknowledges through its expert that GnRH *agonists* were understood at the time of the '082 Patent as useful in IVF procedures. Carr Decl., ¶ 17 ("As of 1987, it was known that administering a GnRH agonist for an extended period of time, about two weeks, causes the GnRH receptors to "down regulate," resulting in suppression of FSH, no LH surge, and no release of the egg. This action does not permanently block ovulation. If administration of the GnRH agonist is discontinued, the receptors will eventually resume normal function."; *id.*, ¶ 21 (stating that GnRH agonists were approved by FDA for use in IVF in 1987); *id.*, ¶ 25 ("As of February 1987, reproductive endocrinologists had been using agonists for [controlled ovarian hyperstimulation] with success."); *see also* Rosenwaks Dep. Tr., T32:23-T34:8. Second, Sun's

[11] In addition to the parties' experts, referenced above, the parties have also supplied extrinsic evidence in the form of scientific articles in support of their respective positions. I have reviewed this evidence and find nothing in it that directly contradicts my finding that the intrinsic evidence does not limit the disputed claim term to contraceptive purposes. The parties cite to articles that show that GnRH antagonists could be used for both pro- and anti-fertility purposes. For that reason, to the extent that some of these articles could be viewed to the contrary of my finding based on the intrinsic evidence, it would nevertheless be inappropriate to rely on this extrinsic evidence to vary or contradict the claims terms. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d at 1583; *see also C.R. Bird, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004).

expert agreed that a person of ordinary skill in the art would have understood in 1987 that GnRH antagonists produce the same effects as GnRH agonists. Carr Decl., ¶ 16 (stating that "both agonist and antagonist can prevent the release of hormone (LH) that causes the release of the egg (i.e., ovulation)"); *id.*, ¶ 19 ("[T]he clinical outcome [of use of GnRH agonists or antagonists] can be similar in that gonadotropin levels are decreased and ovarian (or testicular) function is *suppressed*." (Emphasis added.)); Carr Dep. Tr., at 41:17-44:5; 46:4-14; 67:2-68:2 (same). Finally, the parties' experts agree that it was known to a person skilled in the art at the time of the filing of the '082 Patent that GnRH antagonists could be used in the applications in which a GnRH agonist was used, including delaying ovulation in fertility treatments. See Carr Decl., Ex. H, at 117 ("Logically, all ovarian-*suppressive* indications presently being evaluated for the GnRH agonists would be candidates for use of the GnRH antagonists." (Emphasis added.)).

Thus, the term "inhibiting ovulation" is not inconsistent with the relevant state of the art of the scientific procedures associated with IVF in 1987, as presented by the parties and their experts. The parties agree that in order to successfully preform IVF, *i.e.*, controlled ovarian hyperstimulation, female ovulation must be *both* (i) delayed or suppressed for a period of time, and (ii) then induced. *Compare Markman* Trans., T16:14-19 (Plaintiffs) ("[P]reventing or delaying the woman from ovulating is extremely critical to allow the patient to develop these multiple eggs to maturity so that they can be harvested, and this is what's going to maximize the patient's chances for pregnancy in IVF.") *and id.* at T19:19-T20:1 ("[Ovarian] follicles that previously without ganirelix were at risk for premature ovulation continue to develop because we don't have any LH surge [after application of ganirelix]. This continues until the day when that trigger shot is given . . . [that] causes the eggs to undergo their final maturation process.") *with* Sun Markman Br., Carr Decl., ¶ 22 ("During [controlled ovarian hyperstimulation], the

administration of FSH can cause some women's bodies to react by releasing the surge of LH too early—a premature LH surge—thus causing the release of the eggs before the physician can collect them. The treating doctor may, in effect, shut down the natural hormonal production of both FSH and LH by using extended treatment with a GnRH agonist before stimulation. Doing so has the effect of allowing the egg to mature before it is released from the follicle, ensuring proper ovulation.") *and* Carr Dep. Trans., T54:19-T55:5 ("Q. There were reasons to inhibit ovulation besides preventing pregnancy that were known to people skilled in this art, correct? A. At what period of time? Q. Well, say 1987. A. Yes. I think there was. Q. What are some examples? A. That was to prevent LH surge in an IVF cycle."). Simply put, Sun's contention that the term "inhibiting ovulation" can only refer to contraceptive procedures is contradicted by the experts—"inhibiting ovulation" may equally refer to the portion of controlled ovarian hyperstimulation that involves preventing multiples follicles undergoing premature ovulation. Thus, I reject Sun's contention that a person of ordinary skill in the art at the time of the '082 Patent would not have understood that one of the "known utilities" of a GnRH antagonist, such as ganirelix, could be associated with causing ovulation delay for IVF purposes. Rather, the state of the art was such that a reproductive endocrinologist would be able to recognize that a GnRH antagonist could be used for both contraceptive and fertility purposes.

In view of the foregoing, I find no basis in the intrinsic record or in the state of the art at the time the '082 Patent was filed to limit the term "inhibiting ovulation" to mean contraception. The specification explicitly sets forth "female contraception" and "ovulation prevention or delay" as separate "utilities" of GnRH antagonists. *See* '082 Patent, Col. 11, lns. 47-48. Similarly, as noted, the following column of the specification identifies "inhibition of ovulation" separately from "contraception." *Id.*, Col. 12, lns. 27-28, 44-45. In other words, these terms

are not used interchangeably in the '082 Patent, as Sun argues. Moreover, the state of the art in 1987 was such that GnRH antagonists were being considered for both contraceptive and pro-fertility uses. Given this, I find it inappropriate to define the claim term "inhibiting ovulation" as being limited only to contraception. Indeed, because of the lack of evidence to the contrary, I must give the claim terms the broadest meaning supportable by the patent itself. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999) ("Unless otherwise compelled, a court should give full effect to the ordinary meaning of claim terms, even if the terms are broad."). For that reason, I reject Sun's proposed constructing limiting the phrase "inhibiting ovulation" to contraception only, as that is not the term's broadest possible meaning.[12] *See Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d at 1301-1302. To the contrary, I find that the specification supports a broad interpretation more in line with Plaintiffs' proposed construction, to which I now turn.

Plaintiffs propose a construction of "a method of preventing or delaying ovulation in a female."[13] As an initial matter, Sun argues that Plaintiffs' proposed construction should not be adopted because it is too broad and accordingly would raise questions of enablement. Specifically, Sun relies on language from the Federal Circuit's decision in *Phillips* for the proposition that if a court, "after applying all the available tools of claim construction," still finds

---

[12] Because I disagree with Sun's contention that the claim language is limited to contraceptive purposes, I also reject Sun alternative proposed construction of "a method of female contraception by blocking ovulation," or "a method of female contraception by ovulation prevention or delay."

[13] Plaintiffs first contend that no additional construction is necessary because the plain and ordinary of the disputed claim term is sufficient. As the foregoing discussion makes readily apparent, there is no consensus on what the plain and ordinary meaning should be, thus I find Plaintiffs' proposal to be of little use and inappropriate. *Cf. Funai Electric Co. v. Daewoo Elects. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010) ("The criterion is whether the explanation aids the court and the jury in understanding the term as it is used in the claimed invention.").

ambiguity in a claim, the claim language must be construed "in a manner that would preserve the patent's validity." 415 F.3d at 1327. In that connection, Sun cites two other Federal Circuit decisions, *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed Cir. 1998), and *Athletic Atls., Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996), arguing that it is proper during the patent construction phase for a court, when faced with broad and narrow proposed constructions, to look at whether a broad construction would raise questions of enablement; if so, then the court must adopt the narrower construction. Sun contends that Plaintiffs' proposed broad construction raises questions of enablement because it contains no examples or language indicating the necessary dosage and timing of ganirelix acetate injections for the purposes of delaying ovulation during *in vitro* fertilization.[14]

In response, Plaintiffs reject the notion that questions of enablement are properly considered at the claim construction phase of a patent case. Plaintiffs point out that the *Phillips* court did not actually hold, as Sun suggests, that a court should take into account whether a certain construction would render a patent invalid for lack of enablement, citing *Saunders Group, Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1335 (Fed Cir. 2007). Moreover, Plaintiffs rely on other Federal Circuit case law describing the two primary cases relied on by Sun—*Athletic Alternatives* and *Digital Biometrics*—as "unusual" and limited to very narrow circumstances where a patent applicant has made contradictory representations regarding a contested limitation. *E.g.*, *Housey Pharm., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1356 (Fed. Cir. 2004). Thus, Plaintiffs argue that it is improper for this Court to import an enablement analysis into its claims construction decision. Plaintiffs further argue that, in any event, Sun's enablement arguments are

[14] Sun also asserts that a person of ordinary skill in the art at the time of the '082 Patent would only know how to use ganirelix for female contraceptive purposes; however I have already rejected this argument as unsupported by the evidence.

meritless. Plaintiff relies on the prosecution history of the '082 Patent to show that the Patent Examiner was satisfied that the patent claims were sufficiently enabled after the applicants submitted a letter explaining that the patent claimed "methods of using certain patented [GnRH] antagonists for uses known to be responsive to treatment with [GnRH] antagonists." Finally, Plaintiffs point out that Sun carries the burden of showing lack of enablement, yet has only offered attorney argument, without expert evidence, in support of its claim.

The two cases cited by Sun in support of its enablement argument—*Athletic Alternatives* and *Digital Biometrics*—are "unusual" cases within the Federal Circuit, and thus I find them to be of little application here. The Federal Circuit has recognized that in *Athletic Alternatives*, "the patent applicant made two *contradictory* and *irreconcilable* affirmative representations of the contested limitation. In those circumstances, we held that the narrower interpretation trumps the broader interpretation." *Housey Pharm., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d at 1356. Here Sun has pointed to no contradictory representations made by the applicants of the '082 Patent, and thus I find the rule espoused in *Athletic Alternatives* to be inapplicable. *Id.* Because *Digital Biometrics* simply restates the interpretation principle from *Athletic Alternatives*, it too is distinguished from this matter. Furthermore, I agree with Plaintiffs that Sun has not carried its burden of showing how a broad claim construction, that includes both contraceptive and pro-fertility uses of the claimed method, raises a question of enablement. And in any event, I have found that the intrinsic record and state of the art demonstrate that a GnRH antagonist could be used in pro-fertility applications, and it would be in appropriate to construe the claims more narrowly simply based on Sun's enablement argument. *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999); *AK Steel Corp. v. Sollac & Ugine*, 234 F. Supp. 2d 711, 773 (S.D. Ohio 2002) ("That axiom [that a claim should be interpreted to preserve

its validity] does not permit the Court to re-write the claims in a manner inconsistent with the intrinsic record . . . ."). Accordingly, I reject Sun's argument that a broad interpretation, along the lines of Plaintiffs' proposed construction, must be avoided because of enablement concerns.

In addition to its enablement argument, Sun also contends that Plaintiffs' proposed construction should be rejected because such a construction would render superfluous four of the other methods claimed by the '082 Patent.[15] In that connection, the Federal Circuit has instructed that "claims are interpreted with an eye toward giving effect to all terms in the claim." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006); *see also Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1369-70 (Fed. Cir. 2007) (citing *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987)). In support of its contention, Sun relies solely on its interpretation of the deposition testimony of Plaintiffs' expert, arguing that Dr. Rosenwaks conceded that preventing or delaying ovulation could be associated with several other claimed methods, such as "preventing ovarian hyperstimulation" or "treating endometriosis". *See* Sun Responsive *Markman* Br., 8-9 (citing Rosenwaks Dep. at 131:4-15; 132:13-20; 133:6-10; 135:22-24); *see also* Carr. Supp. Decl., ¶ 5 (citing Rosenwaks Dep.). Review of Dr. Rosenwaks deposition—based on the limited transcript provided[16]—reveals only that, in Dr. Rosenwaks opinion, preventing ovulation could be associated with other claimed methods. Dr. Rosenwaks did not state, as Sun suggests, that Plaintiffs' proposed construction would render the other claimed methods superfluous, and his testimony does not necessarily lead

[15] Specifically, Sun argues that Plaintiffs' proposed construction would also extend to cover the following methods: preventing ovarian hyperstimulation in response to exogenous gonadotropins in a female human subject; treating premenstrual syndrome in a female human subject; threating endometriosis in a female human subject; and treating precocious puberty in a human subject. See Carr Decl., Ex. B at 30:40-47; Carr Supp. Decl., Ex. Q.

[16] Sun supplied only limited excerpts of Dr. Rosenwaks' deposition, and I base my decision on those excerpts accordingly.

to that conclusion. Sun thus has not demonstrated that adopting Plaintiffs' proposed construction of the disputed claim term would necessarily encompass other claim terms. Because Sun presents no other evidence that construing the disputed claim term in accordance with Plaintiffs' proposed construction would violate the above tenets of claim construction, I reject Sun's argument that Plaintiffs' proposed construction is overbroad.

I will therefore adopt Plaintiffs' proposed construction following construction: "a method of preventing or delaying ovulation in female mammals." I am satisfied that this construction aligns with the above findings that the disputed claim term in the '082 Patent should not be construed to explicitly be limited to contraceptive methods only.[17]

IV. CONCLUSION

For the foregoing reasons, the Court construes the disputed claim terms of "a method of inhibiting ovulation in a mammalian female subject"/"a method of inhibiting ovulation in a female mammalian subject" as: "a method of preventing or delaying ovulation in female mammals".

Dated: April 29, 2014

/s/ Freda L. Wolfson
FREDA L. WOLFSON, U.S.D.J.

[17] In that connection, I note that, "a sound claim construction need not always purge every shred of ambiguity." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007). Rather, "after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) *quoted in Acumed, supra* at 806. I am satisfied that my construction set forth above aligns with the specificity and precision of the language of the '082 Patent, and that the fact-finder could make an informed decision based on this construction in an infringement proceeding.